UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v. Case No. 1:24-cv-00995

SACRED HEART REHABILITATION CENTER, INC., PAULA NELSON, and JANIS ROMANIK, D.O., Hon.

Defendants.
_____/

COMPLAINT

The United States of America states the following as its Complaint against the Defendants:

I. INTRODUCTION

1. The opioid epidemic continues to harm Michiganders and their families, friends, and communities. Many communities remain plagued by the effects of this epidemic, marked by thousands of overdose deaths throughout the state.

2. Because of the risk of addiction, misuse, and other diversion of controlled substances—and the inherent risk to patients and others who use these prescription drugs—Congress established the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971. Congress also tasked the U.S. Drug Enforcement Administration ("DEA") with enforcing laws regarding the prescribing, dispensing, and safekeeping of controlled substances.

3. These laws include rules for when medical practitioners may prescribe

and dispense controlled substances, as well as strict recordkeeping and reporting requirements for the handling of controlled substances.

4. When individuals and entities violate these rules, the CSA imposes civil penalties and authorizes the United States to seek injunctive relief.

5. Sacred Heart Rehabilitation Center, Inc. ("Sacred Heart"), a behavioral health and addiction treatment services network, its president and chief executive officer Paula Nelson, and its medical director Janis Romanik, D.O., violated the CSA. They did so by allowing unqualified nursing staff to dispense controlled substances to patients without an appropriate examination by a qualified medical practitioner. And they violated numerous recordkeeping and reporting obligations required by the CSA.

6. This is an action to recover civil penalties and obtain injunctive relief under the CSA against the Defendants for the violations described below.

II. JURISDICTION AND VENUE

7. The Court has jurisdiction pursuant to 21 U.S.C. §§ 842(c)(1), 843(f)(2), and 882(a), and 28 U.S.C. §§ 1331, 1345, and 1355(a).

8. Venue is appropriate in this District pursuant to 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b)(2) and 1395(a).

III. THE PARTIES

9. Plaintiff is the United States of America.

10. Defendant Sacred Heart is a behavioral health and addiction treatment services network. It operates facilities throughout the State of Michigan, including in

the Western District of Michigan. Sacred Heart's corporate offices are located at 400 Stoddard Road, Richmond, Michigan 48062.

11. Defendant Paula Nelson is a resident of the State of Michigan. She is the President and Chief Executive Officer of Sacred Heart.

12. Defendant Janis Romanik, D.O., is a resident of the State of Michigan. She is the Medical Director at Sacred Heart.

IV. LEGAL BACKGROUND

A. The Controlled Substances Act

13. The CSA creates a category of drugs, known as "controlled substances," that are subject to strict federal monitoring and regulation based on their potential for addiction and abuse. Controlled substances are categorized into five schedules based on several factors, including their abuse potential and the likelihood they will cause dependence if misused. A drug becomes a "controlled substance" when it is added to one of these schedules.

14. Schedule III controlled substances have "a potential for abuse less than the drugs or other substances in schedules I and II" but, if abused, "may lead to moderate or low physical dependence or high psychological dependence." *See* 21 U.S.C. § 812(b)(3). Schedule III drugs include buprenorphine, a medication approved to treat opioid use disorder, commonly sold under the brand name Subutex. *See* 21 C.F.R. § 1308.13.

15. Schedule IV controlled substances have "a low potential for abuse relative to the drugs or other substances in schedule III" but, if abused, "may lead to

limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III." *See* 21 U.S.C. § 812(b)(4). Schedule IV drugs include the following:

a. Lorazepam, commonly sold under the brand name Ativan, is a benzodiazepine commonly used to produce sedation, induce sleep, and relieve anxiety. *See* 21 C.F.R. § 1308.14.

b. Phenobarbital is a barbiturate commonly used to treat anxiety and seizures. *See* 21 C.F.R. § 1308.14.

16. Buprenorphine, lorazepam, and phenobarbital are commonly used by substance use treatment centers to treat patients going through withdrawal symptoms.

17. To prevent the diversion of controlled substances, the CSA regulates persons, companies, and other entities that manufacture, distribute, and dispense controlled substances.

B. Registration

18. The CSA and its implementing regulations require those who handle controlled substances, other than the ultimate user, to obtain a controlled substance registration from DEA. 21 U.S.C. §§ 822, 823; 21 C.F.R § 1301. Persons or entities maintaining a controlled substance registration from DEA are referred to as "registrants."

C. Requirements for Prescribing and Dispensing a Prescription for a Controlled Substance

19. In order for a prescription for a controlled substance to be valid, the CSA

requires that it be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 C.F.R. § 1306.04(a). The CSA prohibits prescribing or dispensing a controlled substance that fails to meet those requirements. 21 U.S.C. §§ 829, 842(a)(1).

20. One of the factors in determining whether a prescription for a controlled substance is for a legitimate medical purpose and is being issued in the usual course of professional practice is whether it is being prescribed and dispensed in accordance with state law.

21. In Michigan, state law governing residential detoxification facilities requires that, prior to prescribing or dispensing any medication in the facility, the medical director, a physician, physician assistant, or advanced practice registered nurse must complete and document the medical and drug history, as well as a physical examination, of the patient receiving the medication. Mich. Admin. Code R. 325.1388(6)(a).

22. Further, Michigan law governing the prescribing and dispensing of controlled substances prohibits a licensed prescriber from prescribing a controlled substance unless the prescriber is in a "bona fide prescriber-patient relationship" with the patient for whom the controlled substance is being prescribed. MICH. COMP. LAWS § 333.7303a(2). Michigan law defines a "bona fide prescriber-patient relationship" as one where the prescriber has "reviewed" the patient's relevant medical or clinical records and completed an "assessment" of the patient's medical history and current medical condition, including "a relevant medical evaluation of the

patient conducted in person or through telehealth . . . ." MICH. COMP. LAWS § 333.7104(1).

D. Recordkeeping and Reporting Requirements

23. Recordkeeping and required reporting to DEA are also critical to the closed system of distribution under the CSA and DEA's regulations.

24. As a general matter, DEA registrants must maintain a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant. 21 U.S.C. § 827(a); 21 C.F.R. § 1304.21(a).

25. The CSA and DEA's regulations contain a variety of specific recordkeeping and reporting requirements, including the following applicable to registered practitioners.

26. *First*, a registrant that maintains controlled substances must conduct a biennial inventory of all controlled substances in the registrant's possession. 21 U.S.C. § 827(a); 21 C.F.R. § 1304.11(c).

27. *Second*, a registrant must notify DEA in writing of the theft or significant loss of any controlled substances within one day of discovery and submit a DEA Form 106 regarding the theft or loss. 21 C.F.R. § 1301.76(b).

28. *Third*, each registrant must maintain a complete and accurate record of each controlled substance that it dispenses, including the finished form of the controlled substance and the number of units or volume dispensed. 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.22(c).

D. Personal Liability

29. Under the CSA, non-registrants may also be liable for violations of the CSA.

30. Additionally, responsible corporate officers who have authority to affect an organization's compliance with the CSA may be held personally liable for violations of the CSA.

V. FACTS

A. Background

31. Sacred Heart is a nonprofit organization with a network of treatment centers throughout Michigan that provide behavioral health and addiction treatment services to patients. These services include medication-assisted treatment, residential inpatient treatment, residential withdrawal management (detoxification), and outpatient treatment.

32. Serenity Hills Recovery & Wellness Center ("Serenity Hills") is one of Sacred Heart's treatment facilities, offering detoxification and residential and outpatient addiction treatment. Serenity Hills is located in Berrien Center, Michigan.

33. As part of its treatment services, Serenity Hills dispenses the controlled substances lorazepam, phenobarbital, and buprenorphine to patients in its residential detoxification program who present with symptoms of withdrawal for certain substances, including opioids, alcohol, and benzodiazepines.

34. Sacred Heart's medical director, Dr. Romanik, maintains a controlled

substance registration with DEA that is registered to the Serenity Hills location. Serenity Hills and its staff maintain and dispense controlled substances through Dr. Romanik's DEA certificate of registration.

35. In November 2022, DEA conducted an inspection of Serenity Hills pursuant to an administrative inspection warrant.

36. As part of that inspection, DEA uncovered the following violations of the CSA.

B. Dispensing Violations

37. From November 2021 through December 2022, Defendants unlawfully dispensed controlled substances that were not for a legitimate medical purpose or were outside the usual course of professional practice.

38. Specifically, at Dr. Romanik's direction, nursing staff at Serenity Hills routinely dispensed the controlled substances buprenorphine, lorazepam, and phenobarbital to patients in detoxification prior to a qualified healthcare practitioner examining the patient and conducting a history and physical of the patient.

39. In those instances, Serenity Hills issued and dispensed controlled substances under Dr. Romanik's DEA controlled substance registration, though neither Dr. Romanik nor any other qualified healthcare practitioner first conducted a medical and drug history or physical examination of the patient. As a result, many Serenity Hills patients received controlled substance medication for days without being seen by a qualified healthcare practitioner. In some instances, patients completed their course of controlled substance medication treatment without ever

being seen by a qualified healthcare practitioner.

C. Recordkeeping and Reporting Violations

40. DEA's inspection also revealed recordkeeping and reporting violations, occurring from November 2021 through December 2022.

41. First, Serenity Hills and Dr. Romanik failed to conduct a biennial inventory of all controlled substances at Serenity Hills.

42. Second, despite knowing that three thirty-tablet lorazepam packets had disappeared from Serenity Hills's inventory, Serenity Hills and Dr. Romanik failed to file a timely report of theft or loss with DEA for the missing controlled substances.

43. Third, Serenity Hills and Dr. Romanik failed to keep accurate records of controlled substances dispensed to patients. Specifically, Serenity Hills maintained dispensing logs for each finished form of controlled substances that it dispensed to patients. However, these dispensing logs contained numerous internal inconsistencies and inaccuracies. In some instances, the total dosage amount purportedly dispensed to the patient did not match the number of tablets dispensed. In other instances, the running count of dispensed controlled substance tablets did not add up or was otherwise unclear.

D. Sacred Heart's History of Noncompliance with the CSA

44. Throughout the last twelve years, Sacred Heart and its facilities have a history of noncompliance with the CSA in addition to the violations alleged above.

45. In February 2012, a DEA inspection of a Sacred Heart facility in Madison Heights, Michigan, discovered numerous CSA violations, including that the

facility failed to maintain a biennial inventory and failed to indicate the medication dosage strength on its dispensing log.

46. In September 2013, a DEA inspection of a Sacred Heart facility in Flint, Michigan, discovered multiple CSA violations, including that the facility failed to take a biennial inventory and failed to record the strength of dispensed medication on its dispensing records.

47. In January 2015, a DEA inspection of a Sacred Heart facility in Richmond, Michigan, discovered numerous CSA violations, including that the facility's dispensing records failed to indicate the substance dispensed, the strength of the substance dispensed, and the form of the substance dispensed.

48. In May 2021, a DEA inspection of a Sacred Heart facility in Richmond, Michigan, discovered multiple CSA violations, including that the facility failed to take a biennial inventory.

49. In February 2022, a DEA inspection of a Sacred Heart facility in Richmond, Michigan, discovered multiple CSA violations, including that the facility failed to maintain separate records and inventories for one of the medical doctors registered with DEA at the facility location.

50. In May 2023, a DEA inspection of a Sacred Heart facility in Saint Ignace, Michigan, discovered that the facility violated the CSA by failing to complete an initial inventory of controlled substances.

51. Sacred Heart responded to each of these inspections by purporting to make corrections. Paula Nelson signed response letters to DEA for multiple of these

inspections, including stating in one of the letters: "[W]e are committed to maintaining compliance with all regulatory requirements and feel that the corrective action plan as written will enable us with being compliant."

E. Responsible Corporate Officers

52. Paula Nelson, as Sacred Heart's president and chief executive officer, and Janis Romanik, D.O., as Sacred Heart's medical director, were responsible corporate officers at Sacred Heart, including at the Serenity Hills facility. Both Ms. Nelson and Dr. Romanik had authority to affect Serenity Hills's compliance with the CSA, including with respect to the alleged violations described in Paragraphs 37-43 above.

COUNT I
(Civil Penalties for Unlawful Dispensing of Controlled Substances)

53. The United States repeats and realleges Paragraphs 1 through 52 as if fully set forth herein.

54. The CSA and its implementing regulations prohibited Defendants from dispensing controlled substances without a legitimate medical purpose and outside the usual course of professional practice.

55. Defendants dispensed controlled substances without a legitimate medical purpose and outside the usual course of professional practice by dispensing controlled substances to patients prior to a qualified healthcare practitioner conducting a history or physical examination of the patient, in violation of 21 U.S.C. §§ 829 and 842(a)(1), and 21 C.F.R. § 1306.04(a).

56. As a result of the foregoing, Defendants are liable for penalties of up to

$80,850 for each violation proven at trial. 21 U.S.C. §§ 842(a)(1), 842(c)(1)(A); 28 C.F.R. § 85.5.

COUNT II
(Civil Penalties for Failing to Keep Records and Make Reports)

57. The United States repeats and realleges Paragraphs 1 through 56 as if fully set forth herein.

58. The CSA and its implementing regulations prohibited Defendants from violating the CSA's recordkeeping and reporting requirements.

59. Defendants violated these requirements by failing to take a biennial inventory, failing to report the theft or loss of controlled substances, and failing to maintain complete and accurate controlled substance dispensing records, in violation of 21 U.S.C. §§ 827(a)(3) and 842(a)(5), and 21 C.F.R. §§ 1301.76(b), 1304.11(c), 1304.22(c), and 1305.17.

60. As a result of the foregoing, Defendants are liable for penalties of up to $18,759 for each violation proven at trial. 21 U.S.C. §§ 842(a)(5), 842(c)(1)(B)(i); 28 C.F.R. § 85.5.

COUNT III
(Injunctive Relief)

61. The United States repeats and realleges Paragraphs 1 through 60 as if fully set forth herein.

62. As a result of the violations referred to in Counts I and II, Defendants are subject to injunctive relief pursuant to 21 U.S.C. §§ 843(f) and 882(a).

PRAYER FOR RELIEF

WHEREFORE, the United States demands judgment in its favor and against Defendants as follows:

A. As to Counts I and II, for a maximum statutory penalty in the amounts set forth above for each violation of the CSA proven at trial pursuant to 21 U.S.C. § 842;

B. As to Count III, entry of an order:

1. Declaring that Defendants violated the CSA, specifically 21 U.S.C. §§ 842(a)(1) and 842(a)(5); and
2. Permanently enjoining Defendants from dispensing controlled substances in violation of the CSA and from failing to maintain records and make reports required by the CSA.

C. For interest, attorneys' fees, and costs as allowed by law; and

D. For all such other and further relief as the Court may deem just and proper.

Dated: September 24, 2024

Respectfully submitted,

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